

REMARKS

This paper is submitted in response to the Office Action dated December 4, 2002. Claims 1-11 and 29-37 are currently pending in the application of which claims 1 and 29 are independent claims. Reconsideration of the claims in view of the following arguments is respectfully requested.

The Applicants respectfully traverse the rejections in the pending Office Action being made final. In paragraph 15 on page 11, the Office Action states that Applicants' amendment necessitated new grounds of rejection. The Applicants respectfully disagree on at least two counts.

First, the Applicants disagree that the Applicants amended any of the claims. This assertion is supported in the Office Action in paragraph 1 on page 2 which states that no claims have been amended.

Second, the Applicants respectfully disagree that any new grounds of rejection were necessitated. It is respectfully submitted that the Applicants merely substituted canceled dependent claims to prevent claim 29 standing alone and having no dependent claims, and further that this submission of dependent claims did not require any further searching other than that searching which is ordinarily performed to fill the gaps between Office Action and Applicants' response.

For at least the reasons set forth above, the Applicants respectfully request that the finality of the instant Office Action be withdrawn and that a subsequent Office Action, if necessary, should not be an Advisory Action but rather provide the Applicants an opportunity to advance the application to issue.

In paragraph 4 on page 2 of the Office Action, claim 36 was rejected under 35 U.S.C. § 112 second paragraph for being indefinite. The Applicants respectfully traverse this rejection. Support for the features of this claim can be found on at least page 27, lines 1-8 of the specification. The Applicants respectfully submit that a sharp edge can have a radius of curvature. For example, when a can of vegetables is opened and the top is removed by a can opener, the removed top demonstrates a sharp edge having a radius of curvature. It is understood that the radius of curvature may reside along a different axis than an axis chosen to demonstrate that an edge is sharp.

For at least the reasons set forth above, the Applicants respectfully submit that claim 36 does particularly and distinctly claim the subject matter of the Applicants' claimed invention and therefore is asserted to comply with 35 U.S.C. § 112. The Applicants respectfully request that the rejection be withdrawn.

In paragraph 6 on page 3 of the Office Action, claims 1-2, 5-7, and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by Jansen. The Applicants respectfully traverse the rejections and request reconsideration of the claims in view of the following arguments.

To anticipate a claim, a reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the cited reference to maintain a rejection based on 35 U.S.C. § 102. The Applicants respectfully submit that Jansen fails to teach every element of claim 1, and therefore fails to anticipate claim 1. The Applicants respectfully request reconsideration of claim 1 based on the following comments.

The Applicants set forth in claim 1, a mandrel including a top surface and an outer surface. The outer surface includes a plurality of ridges. Contoured surfaces extend between the ridges and correspond to polymer leaflets. An edge on the mandrel separates the top surface and the contoured surfaces. The mandrel edge corresponds to the free edge of the leaflets.

The Applicants' mandrel includes contoured surfaces to provide a desired shape for the leaflets. The contoured surfaces, as shown in Figs. 8-14, for example, are curved or form a complex curve.

Jansen is different from the Applicants' claimed invention. Jansen teaches a dip mould (mandrel) which has shaping surfaces for the closing elements, i.e., the sails, of a heart valve to be formed. The shaping surfaces have a two dimensional curvature and predetermine the shape of the closing member in the closed condition of the heart valve

(col. 1, lines 30-36). The dip mould (mandrel) shown in Fig. 1 has a cylindrical portion 2 and a conical portion 3 which is triangularly formed in top view, as shown at 8. Three mould surfaces 5 which are substantially planar (slightly curved towards the upper end of the dip mould) are located within the range of the conical portion 3 (col. 6, line 63 through col. 7, line 2). The surfaces 5 of the mandrel are planar (col. 6, lines 67-68).

Jansen is different from the Applicants' claimed invention because the mandrel of Jansen is provided with planar surfaces whereas the mandrel set forth in Applicants' claim 1 is provided with contoured surfaces.

Further, Jansen teaches post 6 serves as a commissure support for attachment of the free edge of the leaflets. Thus, the free edge of the leaflets do not extend beyond the peak of post 6. Moreover, because post 6 does not extend to the top surface 8 of the mandrel, the edge separating the top surface from surfaces 5 can not correspond to the free edge of the fabricated leaflets.

Jansen is different from the Applicants' claimed invention because the top surface of the mandrel of Jansen does not correspond to the free edge of the fabricated leaflets whereas the top surface of the mandrel set forth in Applicants' claim 1 is adapted to correspond to the free edge of the fabricated leaflets.

For at least the reasons set forth above, the Applicants respectfully submit that Jansen fails to teach all the features set forth in Applicants' independent claim 1 and therefore fails to anticipate claim 1. Claim 1 is thus allowable over the cited reference. The Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Jansen. The Applicants respectfully request that the rejection be withdrawn.

Dependent claims 2, 5-7 and 10, which are dependent from independent claim 1, were also rejected under 35 U.S.C. § 102(b) as being unpatentable over Jansen. While the Applicants do not acquiesce to the particular rejections of these dependent claims, it is asserted that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2, 5-7 and 10 are

also in condition for allowance. The Applicants respectfully request that the rejection of claims 2, 5-7 and 10 be withdrawn.

In paragraph 7 on page 3 of the Office Action, claims 1-2, 5-7, 10, and 30 were rejected under 35 U.S.C. § 102(b) as being anticipated by NL 1008349 (Bosch). The Applicants respectfully traverse the rejections and request reconsideration of the rejections based on the following arguments.

The Applicants' claim 1 was set forth above. The Applicants' mandrel includes contoured surfaces to provide a desired shape for the leaflets of the heart valve. The contoured surfaces, as shown in Figs. 8-14, are curved or form a complex curve. Additionally, the edge on the mandrel separates the top surface and the contoured surfaces, and has a mandrel edge that corresponds to the free edge of the leaflets.

Bosch teaches a two piece mold, not a mandrel, in which a leaflet is formed between the two pieces when the mold is positioned together. There is no edge on the mold that separates the top surface and the contoured surfaces, as set forth in Applicants' claim 1, or a mandrel edge that corresponds to the free edge of the leaflets. Referring to Fig. 8B of Bosch, surfaces 84 of the mold are flat. The mold does not have contoured surfaces, as set forth in Applicants' claim 1.

Bosch is different from the Applicants' claimed invention because Bosch does not disclose contoured surfaces or a mandrel edge which corresponds to the free edge of the leaflets, or an edge that separates the top surface and the contoured surfaces, as set forth in Applicants' claim 1. Thus, Bosch does not establish prima facie anticipation of Applicants' claimed invention. The Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) in view of Bosch.

Dependent claims 2, 5-7, 10 and 30, which are dependent from independent claim 1, were also rejected under 35 U.S.C. § 102(b) as being unpatentable over Bosch. While the Applicants do not acquiesce to the particular rejections of these dependent claims, it is asserted that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent

claims 2, 5-7, 10 and 30 are also in condition for allowance. The Applicants respectfully request that the rejection of claims 2, 5-7, 10 and 30 be withdrawn.

In paragraph 8 on page 4 of the Office Action, claims 1, 8, 11, 29, and 31 were rejected under 35 U.S.C. § 102(b) as being anticipated by Pierce. The Applicants respectfully traverse the rejections and request reconsideration of the rejections in view of the following arguments.

Applicants' claim 1 is set forth above. The Applicants set forth in independent claim 29, a mandrel including an outer surface having a plurality of ridges and contoured surfaces extending between the ridges. The contoured surfaces correspond to polymer leaflets in a closed configuration. The contoured surfaces corresponding to the leaflets meet contoured surfaces of adjacent leaflets at a sharp edge.

Pierce is different from the Applicants' claimed invention. Pierce does not disclose a mandrel edge corresponding to a free edge of the leaflet as set forth in the Applicants' claims 1 and 29. Pierce fails to teach a mandrel having an edge corresponding to the free edge of a leaflet. As shown in Fig. 11, the free edge of the leaflet (40) is along the middle of the top of shim 35. The free edge of the leaflet is along a surface along the top of the mandrel, not along an edge of the mandrel.

Further, Pierce discloses the cutting of adjacent leaflets to form the free edge. See, for example, column 4, lines 11-13 and corresponding Figs. 11 and 12. Pierce also fails to teach a mandrel where contoured surfaces that correspond to the leaflets meet contoured surfaces of adjacent leaflets at a sharp edge. Pierce teaches the leaflet free edges meeting along a top surface, not an edge. The free edges of the leaflets are located along the top of the shim not at a sharp edge as set forth in the Applicants' claimed invention.

Pierce is different from the Applicants' claimed invention because Pierce fails to disclose a mandrel with an edge corresponding to the free edge of the leaflet as set forth in Applicants' claims 1 and 29. Pierce does not establish prima facie anticipation of claims 1 and 29.

Dependent claims 8, 11 and 31 which are dependent from independent claim 1, were also rejected under 35 U.S.C. § 102(b) as being unpatentable over Pierce. While the Applicants do not acquiesce to the particular rejections of these dependent claims, it

is asserted that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 8, 11 and 31 are also in condition for allowance. The Applicants respectfully request that the rejection of claims 8, 11 and 31 be withdrawn.

In paragraph 10 on page 5, claims 3-4, 9, and 32-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jansen or Bosch in view of Moe and Stockum. In paragraph 11 on page 7, claim 35 was rejected over Jansen or Bosch and Hennig. In paragraph 12 on page 8, claim 36 was rejected over Pierce and Moe. In paragraph 13 on page 9, claim 37 was rejected over Pierce and Hennig. The Applicants respectfully traverse the rejections as set forth below.

Dependent claims 3, 4, 9 and 32-37, which are dependent from independent claims 1 and 29, were rejected under 35 U.S.C. §103(a) as being unpatentable over various combination of Jansen, Bosch, Pierce, Stockum, Moe and Hennig. While the Applicants do not acquiesce to the particular rejections of these dependent claims, it is respectfully asserted that these rejections are moot in view of the remarks made in connection with independent claims 1 and 29. These dependent claims include all of the features of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 3, 4, 9 and 32-37 are also in condition for allowance. The Applicants respectfully request that the rejections be withdrawn.

In response to the arguments raised in the Office Action, the free edge extending beyond the peak and being in the middle of the shim provide further evidence of differences that exist between the Applicants' claimed invention and the cited references. The Applicants are merely localizing the edge to clarify an understanding of the differences between the instant invention and cited references. The other arguments are directed to the dependent claims which are held to be moot in view of the asserted allowability of independent claims 1 and 29.

In view of the reasons provided above, it is asserted that all pending claims are in condition for allowance. The Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please feel free to contact Agent for the Applicants', Fredrick T. French III at (952) 253-4123.

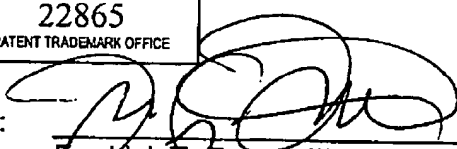
Respectfully submitted,

Altera Law Group, LLC



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